OCT 1 7 2000

K002913

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Entific Medical System summary for the Headband for BAHA.

SUBMITTER'S NAME:	Entific Medical System
ADDRESS:	P.O. Box 16024
	SE-412 21 Göteborg
	Sweden
CONTACT PERSON:	Constance Bundy
TELEPHONE NUMBER:	612-574-1976
FAX NUMBER:	612-571-2437
DATE OF SUBMISSION:	September 15, 2000

1. **Identification of device**
   Proprietary Name: Headband for BAHA
   Common Name: Headband for Bone Conduction Hearing Aid
   Classification Status: Class II per regulations 874.3300
   Product Codes: LXB

2. **Equivalent devices**
   Entific Medical System believes the Headband for BAHA is substantially equivalent to the headband used with the Second Ear Bone Conduction Hearing Aid, cleared for marketing under 510(k) K953872.

3. **Description of the Device**
   The BAHA is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the middle ear.

   The BAHA is usually connected to a fixture pillar, which has been surgically placed in the bone behind the ear. Use of the headband allows the BAHA to be held against the skin behind the ear. With the headband, there is no fixture pillar implanted. See B.3 System Diagram. BAHA with headband consists of the same components as the BAHA Classic 300 and Cordelle II minus the components necessary for the surgical attachment.

4. **Intended use**
   The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive

losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

5. Technological characteristics, comparison to predicate device.

Comparison table

Characteristic	**Predicate device: Second Ear – Bone Conduction Hearing Aid**	**Headband for BAHA**
Material	Medical Grade Plastic	Peek
Intended Use	Moderate to severe conductive hearing losses. Particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.	Same
Power requirement	4.8 VDC Nickel-Metal-Hybride Battery	R675 Zink Air – BAHA Classic 300 Nickel-Metal-Hybride 9V 6F22 – BAHA Cordelle II
Max gain	57dB	33 dB – BAHA Classic 300 55 dB – BAHA Cordelle II
Frequency response	150 Hz – 8 KHz	125 Hz – 8 KHz
Manufacturer	Wordcomp International	Entific Medical Systems
Classification code	LXB	Same
K-number	K953872	Pending

7. Conclusion

It is the conclusion of Entific Medical System that the Headband for BAHA is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2000

Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K002913
Trade Name: Headband for BAHA
Regulatory Class: II
Product Code: 77-LXB
Dated: September 15, 2000
Received: September 18, 2000

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. INDICATIONS FOR USE

510(k) Number K002913

Device Name: Headband for BAHA

Indications for Use:

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002913